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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,110	11/18/2005	Jerome Siegel	2307AA-128410US	2706

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,110	SIEGEL ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/05,3/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed 28 February 2005 has been entered. Claims 18 – 26 and 30 – 36 have been canceled; claims 1 – 17 and 27 – 29 are pending and under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 17 and 27 – 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of hypocretin and subsequent short-term increase in locomotor activity, does not reasonably provide enablement for administration of agonists of undisclosed structure or for preventing or treating excess body weight as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

In the instant case, the nature of the invention is complex. The claims encompass administration of any agonist of hypocretin, independent of its structure. While hypocretins (also known as orexins, see specification paragraphs [04] and [46]) were well-known in the art, the full genus of agonists, which are to be administered in the claimed methods, were not known in the art and furthermore are not disclosed in the specification. While the specification discloses administration of hypocretin, it does not disclose to the skilled artisan how to make the agonists of same which are required as starting materials for the claimed invention.

In order to practice the full scope of the claimed invention, the skilled artisan would have to discover, on his or her own, the agents which are hypocretin agonists. These are required starting materials for the claimed methods, but the specification does not teach the artisan how to make and use these materials, or from which sources they should be purchased.
The disclosure screening assays, such as those mentioned at paragraph [56] – [65] of the specification, is not sufficient to indicate how to actually make (or obtain) the starting materials. The specification does not disclose to the artisan how to make the full genus of compounds that might be found in the screening assay, as what is identified in the screening assay is entirely dependent upon what chemical compounds are screened. Furthermore the art recognizes that a molecule's function is dependent upon its structure. For example, Alberts et al. (1994. Molecular Biology of the Cell pp. 129 – 130) teaches that protein function is determined by shape. Of course the same logic applies to molecules that are agonists of hypocretin, as they must interact with the either protein itself or its receptor. While screening assays to discover agents could in theory be performed, the structures of agents identified in the assays are entirely dependent upon what structures are tested. Thus the artisan would have to resort to undue experimentation to practice the claimed method, as the artisan would have to invent or discover the appropriate agents on his or her own. Given the lack of guidance as to what structures should be used, the large degree of experimentation that would have to be undertaken to make the agents required in the claimed methods would be undue.

Additionally, the specification is not enabling for methods of preventing or treating excess body weight. The specification discloses no working examples of decreasing body weight in overweight subjects, and discloses no working examples of preventing increases in body weight, for example in subjects who are not yet overweight. At the time the invention was made, the art recognized that hypocretins (also called orexins) are proteins that increase food intake. See for example Haynes (1999. Peptides 20:1099-1105, cited on IDS filed 15 March 2006), particularly Figure 1 which indicates that orexin-A increases food consumption as compared to control injections. See also Preti (2002. Current Opinion in Investigational Drugs 3(8):1199-1206, cited on IDS filed 15 March 2006), who teaches that injection of orexins can result in up to 10-fold increase in food intake (p. 1199, first sentence of Introduction); note the reference teaches that SB-334867-A, an orexin (hypocretin) antagonist, decreases feeding (p. 1199 second column). As the specification shows no examples of weight reduction or inhibition of weight gain by administration of hypocretin, and the art recognized that hypocretin induces

food consumption, the skilled artisan would not be able to practice the method of claims 1 – 16 in such a manner as to achieve the stated goals. Given large degree of experimentation required to practice the invention, and given the lack of adequate guidance and working examples in the specification, coupled with the intent of the methods which are contrary to what is recognized in the art, it would take undue experimentation for the skilled artisan to practice the invention commensurate in scope with the claims.

3. Claims 1 – 17 and 27 – 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Independent claims 1, 17, and 27, as well as dependent claim 15, each encompass administration of “hypocretin or an agonist thereof”. This term is not fully described in the specification, for two reasons. First, applicant has defined the term “hypocretin” to include molecules of undisclosed structure. At paragraph [46] of the specification, applicant has indicated that the term includes several known proteins, and refers to specific scientific articles as disclosing the structures of those proteins. These of course, are described. However, applicant has also expanded the definition to include “the amino acid sequences discussed below, and allelic, cognate, or induced variants thereof.” The specification also indicates that recitation of the term "hypocretin" refers to “fragments of hypocretin peptide having the same or similar functional effect as hypocretin... the term hypocretin can also refer to an agonist thereof.” Thus by reciting “hypocretin” in the claims, applicant is encompassing any allelic, cognate, or induced variant, including those not described, with any number of possible changes in the sequence. Applicant is also encompassing any agonist by recitation of “hypocretin”, including those of unknown or undisclosed structure, which may be later found by screening assays.

The agonists, both encompassed in the term “hypocretin” as defined by applicant in the specification and explicitly recited in claims 1, 15, 17, and 27 are not described by the specification. The claims are drawn to administration of molecules defined by what they do, not by what they are. The specification fails to actually set forth the structure of the molecules which are to be administered in the claimed methods. The specification describes screening assays (paragraphs [56] – [65]) which might be used to identify molecules that have the

requisite function. However, no structurally defined compounds are encompassed by the term "an agonist thereof". Because no structure beyond hypocretin (which is in fact defined to include agonists) is listed in the claims, the skilled artisan could not determine what structures are encompassed by the claims. Rather than describing to the public the actual invention, the claims and specification describe to the public a plan for obtaining it. Of course what is actually identified in the screening assay depends upon what compounds are screened. If a library of antibodies is screened, the assay might identify some antibodies. If a library of small organic molecules is screened, the assay might identify some small organic molecules. However, knowing how to do the steps of the assay does not describe the invention now claimed, which is a method of administering a compound.

The instant disclosure of screening assays does not adequately support the scope of the claimed genus, which encompasses administration of a substantial variety of subgenera of unlimited structure. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

Here, applicant has not described a reasonable number of members of the genus of materials to be administered to patients, but rather has presented the public with an idea of how to perform an assay that might identify some agents that could be administered. Of course, depending on what agents are used in the screening assay, it may well identify none.

The instant claims are often referred to as "reach-through" claims, where an applicant attempts to obtain patent protection on an invention not yet discovered. The Court of Appeals for the Federal Circuit addressed claims of this sort in great detail in *University of Rochester v.*

G.D. Searle and Co. (69 USPQ 2nd 1886, CAFC 2004). In *Rochester*, the Federal Circuit upheld the district court's ruling that patent claims which recited administration of compounds not disclosed, but rather to be identified in a screening assay, were invalid on their face. While the instant claims do not actually recite steps of a screening method, they are read in light of the specification, which clearly describes such methods. Thus the situation is analogous to that in *Rochester*. Since the specification does not disclose to the public the structures to be administered in the claimed methods, it does not meet the written description requirement of 35 USC § 112, first paragraph. Thus, claims 1, 15, 17, and 27 are rejected. The remaining claims depend from a rejected base or intermediate claim but are not limited to subject matter fully described by the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 17 and 27 – 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 17, and 27 each recite the phrase "hypocretin or an agonist thereof". This language implies that hypocretin and its agonists are mutually exclusive alternatives; i.e. either hypocretin protein or an agonist of hypocretin protein could be as recited in the method. Further, this language indicates that "hypocretin" is not to be considered to be inclusive of an agonist of hypocretin. However, the specification (paragraph [46]) clearly has defined "hypocretin" to include agonists of hypocretin. Thus the scope of claims which recite "hypocretin or an agonist thereof" is unclear. Is "hypocretin", as recited in the claims, to be construed to encompass the agonists (as defined in the specification) or is it to exclusive of agonists, as implied by the claims? Thus claims 1, 17, and 27 are indefinite. The remaining claims depend from a rejected base or intermediate claim but fail to resolve this ambiguity.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 14 – 17, and 27 – 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiyashchenko (May 2001. Journal of Neurophysiology 85:2008 – 2016, cited as reference AG on IDS filed 6 June 2005).

Kiyashchenko teaches microinjection of orexin-A and orexin-B into mammals. Orexin is a synonym for hypocretin (specification, paragraph [04]). The sole step required for claims 1, 17, and 27 is the administration. Each of these independent claims encompasses administration to asymptomatic subjects; note claim 1 encompasses prevention of excess body weight, and claims 17 and 27 each recite certain effects which will occur upon administration. As the reference by Kiyashchenko teaches administration of the same material to the same subjects as now claimed, it anticipates the invention. Note the reference explicitly teaches increasing muscular activity (see p. 2010 first column final paragraph), as recited in claim 17. This increase in muscular activity is consistent with the intent of claim 27, namely increasing metabolism.

Claim 14 is rejected as it recites effects which will necessarily happen upon administration. Claim 15 is anticipated as Kiyashchenko teaches administration of orexin (hypocretin) in saline, which is a pharmaceutically acceptable carrier (see p. 2009, first column, second paragraph of the section entitled “Microinjection”). Claim 16 is anticipated as the animals are free of narcolepsy. Claim 28 is rejected as the increase in muscle activity results in increased metabolism.

6. Claims 1, 4 – 6, 14 – 17, and 27 – 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Haynes (1999. Peptides 20:1099-1105, cited as reference AG on IDS filed 15 March 2006).

Haynes teaches administration of orexin, which is a synonym for hypocretin. The reference teaches that orexin administration results in no increase in body weight after either two or eight days; see Table 1 on p. 1103. Note that all three groups (vehicle, orexin-A, and

orexin-B) have the same body weight on the days of weighing. Thus Haynes teaches a method of preventing excess body weight in an individual comprising administering a hypocretin, as recited in claim 1.

Claims 4 – 5 are anticipated Haynes teaches monitoring body weight. Claim 6 is anticipated as Haynes teaches several routes of administration, including i.c.v., i.v., and s.c., each of which is recited in claim 6. Claim 14 is anticipated as it requires no additional steps beyond administration; rather claim 14 recites effects which will necessarily occur upon administration. Claim 15 is anticipated as the reference teaches administration in water and in saline (p. 1100 second column), each of which is a pharmaceutically acceptable carrier. Claim 16 is anticipated as the subjects are free of narcolepsy. Claims 17 and 27 – 28 are anticipated as they require no steps beyond administration of the compound, rather the claims recite effects which will necessarily occur upon administration.

7. Claims 1, 6, 14 – 17, and 27 – 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Siegel (U.S. Patent 7,112,566, issued 26 September 2006, filed 11 May 2000, claiming benefit of earlier-filed applications).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Note that the claims of the '566 patent anticipate several of the instant claims and thus declarations under 37 CFR 1.131 may not be effective to overcome those aspects of the rejection.

Siegel teaches and claims methods of administering hypocretin to subjects. See for example Siegel's claims 1 and 6. As instant claims 1, 17, and 27 require nothing other than administering hypocretin to a subject, Siegel '566 patent anticipates these claims. Siegel also teaches various route of administration as recited in instant claim 6; see for example Siegel's claims 12 and 13. Claim 14 is anticipated as it requires no additional steps beyond administration; rather claim 14 recites effects which will necessarily occur upon administration. Claim 15 is anticipated as the reference teaches administration in pharmaceutically acceptable carriers; see column 21 line 60 – column 23 line 55 for example. Claim 16 is anticipated as

Siegel '566 patent teaches treatment of several sleep disorders other than narcolepsy; see for example column 12 line 25 – column 18 line 35. Claim 28 is anticipated as it requires no steps beyond administration of the compound, rather the claim recites effects which will necessarily occur upon administration.

8. Claims 1, 6, 14 – 17, and 27 – 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Siegel (U.S. Patent 7,335,640, issued 26 February 2008, effective filing date at least 11 May 2000, claiming benefit of earlier-filed applications).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Note that the claims of the '640 patent anticipate several of the instant claims and thus declarations under 37 CFR 1.131 may not be effective to overcome those aspects of the rejection.

Siegel teaches and claims methods of administering hypocretin to subjects. See for example Siegel's claims 1 and 8. As instant claims 1, 17, and 27 require nothing other than administering hypocretin to a subject, Siegel '640 patent anticipates these claims. Siegel also teaches various route of administration as recited in instant claim 6; see for example Siegel's claims 7 and 15. Claim 14 is anticipated as it requires no additional steps beyond administration; rather claim 14 recites effects which will necessarily occur upon administration. Claim 15 is anticipated as the reference teaches administration in pharmaceutically acceptable carriers; see Siegel '640 patent claim 18. Claim 16 is anticipated as the patent teaches treatment of several sleep disorders other than narcolepsy, see for example Siegel '640, column 11 lines 10 – 28, column 12 line 10 – column 17 line 11. Claim 28 is anticipated as it requires no steps beyond administration of the compound, rather the claim recites effects which will necessarily occur upon administration.

Claims 1, 6, 14 – 17, and 27 – 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Taheri (2001), "The Role of Orexins in the Regulation of Appetite, Sleep and Arousal, Abstract Number Y16 presented at Spring Meeting, Royal College of Physicians,

London, on 1 June 2001). Note the abstract was later published in Clinical Science (2001) 101(2, Supplement 45):17p. However the enclosed Table of Contents and face page for the conference proceedings from that issue clearly indicate the disclosure to those skilled in the art was on 1 June 2001, more than a year before the earliest effective filing date of the instant application. Such public disseminations constitute printed publications within the meaning of 35 USC 102(b); see MPEP 2128, which states:

> A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." In re Wyer, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting I.C.E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966))

See also MPEP 2128.01(IV).

Taheri teaches administration of orexin-A to rats increases activity in the first four hours after such administration; see middle of first paragraph. Orexin is a synonym for hypocretin. The reference teaches every active step of claim 1, i.e. administering a hypocretin to an individual. The reference also teaches that administration increases activity, which is construed by applicant as being effective to prevent excess body weight (specification, paragraphs [11] and [113] as well as Figure 1). Thus the reference by Taheri anticipates claim 1.

Claim 6 is anticipated as injection by Taheri was i.c.v. Claim 14 is anticipated as it requires no additional steps beyond administration; rather claim 14 recites effects which will necessarily occur upon administration. Although Taheri is silent with respect to the presence of a pharmaceutically acceptable carrier, it is reasonable that such a carrier was in fact present, as proteins such as orexin (hypocretin) cannot be administered i.c.v. in dry form. Thus claim 15 is anticipated. Claim 16 is anticipated as the rats used are not disclosed as being narcoleptic. Claim 17 is anticipated as Taheri teaches that administration of orexin increases motor activity (note Taheri uses the term "significantly increased active behavior"). Claim 27 is anticipated as Taheri shows that administering orexin increases activity, which will increase metabolism. Claim 28 is anticipated as it requires no steps beyond administration of the compound, rather the claim recites effects which will necessarily occur upon administration.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 14 - 15, 17, and 27 - 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 16 of U.S. Patent No. 7,112,566. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims encompass administration of hypocretin to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '566 patent the claims are more specific in that they are drawn to administration to specific patient populations.

10. Claims 1, 14 - 15, 17, and 27 - 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of U.S. Patent No. 7,335,640. Although the conflicting claims are not identical, they are not patentably distinct from

each other because in the instant case the claims encompass administration of hypocretin to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '640 patent the claims are more specific in that they are drawn to administration to specific patient populations.

11. Claims 1, 14 - 15, 17, and 27 - 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of copending Application No. 11/937891. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims encompass administration of hypocretin to subjects including for prophylaxis, or without any particular disease or condition listed, whereas in the '891 case the claims are more specific in that they are drawn to administration to specific patient populations.

.This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship

12. Claims 1, 14 – 15, 17, and 27 – 28 are directed to an invention not patentably distinct from claims of commonly assigned U.S. Patents 7,112,566 and 7,335,640 and application 11/937891 as set forth in the double-patenting rejections above.

13. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 7,112,566 and 7,335,640 and application 11/937891, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the

commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Note no assignment was filed in this case upon entry to the national stage. Thus there is not evidence that the inventions were commonly owned at the time of invention of the subject matter claimed in this case.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
February 29, 2008